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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,051	07/24/2006	Dalia Cohen	33424-US-PCT	1581

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
01/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,051	COHEN ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 9-12, drawn to a method to treat neurodegenerative conditions comprising administering a modulator of a protein selected from Table 3 or Table 3A, wherein the modulator comprises one or more antibodies to said protein and inhibits said protein.

Group II, claim(s) 1-2, 6-7, 9-10, 14-15, drawn to a method to treat neurodegenerative conditions comprising administering a modulator of a protein selected from Table 3 or Table 3A, wherein the modulator comprises one or more oligonucleotides to said protein and inhibits said protein.

Group III, claim(s) 1-2, 8-10, 13, 16, drawn to treat neurodegenerative conditions comprising administering a modulator of a protein selected from Table 3 or Table 3A, wherein the modulator enhances said protein.

Group IV, claim(s) 17-24, drawn to a method to identify modulators useful to treat neurodegenerative conditions, wherein the modulators modulate a protein selected from Table 3 or Table 3A.

Group V, claim(s) 25-28, drawn to a pharmaceutical composition comprising a modulator of a protein in Table 3 or Table 3A, wherein the modulator comprises one or more antibodies to said protein and inhibits said protein.

Group VI, claim(s) 25-27, 30-31, drawn to a pharmaceutical composition comprising a modulator of a protein in Table 3 or Table 3A, wherein the modulator comprises one or more oligonucleotides to said protein and inhibits said protein.

Group VII, claim(s) 25-26, 29, 32, drawn to a pharmaceutical composition comprising a modulator of a protein in Table 3 or Table 3A, wherein the modulator enhances said protein.

Group VIII, claim(s) 33-34, drawn to a method to diagnose subjects with neurodegenerative conditions comprising assaying expression levels of proteins disclosed in Table 3 or Table 3A.

Group IX, claim(s) 35-36, 38-40, 42, drawn to a method to treat a neurodegenerative comprising assaying for expression levels of a protein selected from Table 3 or Table 3A and administering a modulator that inhibits said protein.

Group X, claim(s) 35-37, 39-41, drawn to a method to treat a neurodegenerative comprising assaying for expression levels of a protein selected from Table 3 or Table 3A and administering a modulator that enhances said protein.

Group XI, claim(s) 43-44, drawn to a diagnostic kit for detecting levels of a protein in Table 3 or Table 3A. If this group is elected, applicant is further required to elect a single disclosed component from (a)-(e). Note that this is not a species election requirement.

In addition to electing a single inventive group listed above, applicant is further required to elect a single disclosed gene listed in Table 3 or Table 3A. Note that this is not a species election requirement.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of groups I-XI are found to have no special technical feature that defines a contribution over the prior art of Rhim et al. (*Mammalian Genome,* 1997, 8:872-873).

The first claimed invention in the instant case is a method to treat neurodegenerative conditions with a modulator of MGC10182, which is synonymous with human SLUG or SLUGH. Rhim et al. teach that the Slug gene is a neurogenic transcription factor and that the protein SLUG is critical in the developing brain, thereby suggesting that modulators of SLUGH can be used as agents for treating neurodegenerative conditions. See the entire reference. Since MGC10182 is the first gene listed in Table 3, and since the use of MGC10182 in the claimed method was suggested in the art by Rhim et al., applicant's invention does not contribute a

special technical feature when viewed over the prior art of Rhim et al. Accordingly, the inventions of groups I-XI as well as genes listed in Table 3 and Table 3A do not have a single inventive concept and so lack unity of invention, and therefore the restriction for examination purpose as indicated is proper.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed diagnostic kit agents, the Marksuh group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant diagnostic kit agents are considered to be each separate invention for the following reasons:

As described above, the agents do not meet the criteria of (A), common property or activity and (B)(1), common structure or (B)(2), art recognized class of compounds. Although all agents are disclosed as potential diagnostic agents, each agent behaves in a different way in the context of the claimed invention. For example, an antibody comprises amino acids and binds

a cognate antigen whereas an RNAi sequence comprises ribonucleotides and binds a target mRNA sequence. Hence, the agents do not have common property or activity, nor do they share a common structure. Further, the agents are not recognized as same class of compounds. Accordingly, unity of invention between the agents is lacking and each agent claimed is considered to constitute a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/Dana Shin/
Examiner, Art Unit 1635